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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,921	09/22/2003	Ioana M. Rizoiu	BI9100CIPCON	9901

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EXAMINER	
SHAY, DAVID M	
ART UNIT	**PAPER NUMBER**
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,921	RIZOIU ET AL.	
	Examiner	Art Unit	
	david shay	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 20, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *July 20,* _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The drawings are objected to because Figure 11c contains elements that are not labeled with indicia indicative of their function. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The amendment filed July 20, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the incorporation by reference of the disclosures of applications OTHER than 09/188,072; the inclusion of 60/064,465 in the continuing data; and the limitation that obstructions are not present between the cannula lumen and an area of tissue located distally of the open cannula distal end.

Applicant argues that Figures 9b and 10b of the original disclosure and the reference to an "open cannula configuration" provide support for the phrase "obstructions are not present between the cannula lumen and an area of tissue located distally of the open cannula distal end". However, the referenced disclosure and Figures merely provides support for the cannula end being open, not for there being no obstruction beyond (located distally of) the end of the cannula. Thus this argument is not convincing.

It is noted that the openings in the tip of Massengill provide no obstruction between the distal tip of the device and the tissue distal thereof.

The examiner has taken official notice that of the obviousness of configuring devices for and using devices for the removal of fat in joints or the abdomen since these are known sites of fat tissue; to employ sterile fluids, since this prevents infection when operating on internal tissue; to construct the device from medical grade plastics, since this is a notorious material for medical devices; and to construct the device of stainless steel, since this is a notorious material for medical devices and is inert. Applicant has not challenged these determinations and they are now considered admitted prior art.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. The originally filed disclosure is silent on "obstructions are not present between the cannula lumen and an area of tissue located distally of the open cannula distal end".

Claims 27-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rizoiu et al (WO '928) in combination with Massengill and the admitted prior art of configuring devices for and using devices for the removal of fat in joints or the abdomen since these are known sites of fat tissue; to employ sterile fluids, since this prevents infection when operating on internal tissue; to construct the device from medical grade plastics, since this is a notorious material for medical devices; and to construct the device of stainless steel, since this is a notorious material for medical devices and is inert. Rizoiu et al teach a tissue removal device and method with hydrokinetic energy generated by the claimed lasers and using water, epinephrine and/or anesthetic as the fluid. Messangill teaches the removal of fat tissue using a cannula which delivers hydrokinetic energy to the tissue to be removed. It would have been obvious to the artisan or ordinary skill to employ the hydrokinetic energy generators and steps and fluids of Rizoiu et al (WO '928) in the method and device of Massengill, since Massengill teaches no particular laser and since the claimed fluids are equivalent and or compatible with water when generating the hydrokinetic energy, as taught by Rizoiu et al (WO '928); or to employ the cannula delivery system and steps of Massengill in the device and method of Rizoiu et al (WO '928) , since Rizoiu et al (WO '928) teaches that the device and method can be used on many kinds of tissue and can include many different types of instruments; and in either case, to employ the method on and configure the device for removal of fat tissue in joints or the abdomen since these are known sites of fat tissue, official notice of which has already been taken, to employ sterile fluids, since this prevents infection when operating on internal tissue, official notice of

which has already been taken, to construct the device from medical grade plastics, since this is a notorious material for medical devices, official notice of which has already been taken, and to construct the device of stainless steel, since this is a notorious material for medical devices and is inert, official notice of which has already been taken, thus producing a device and method such as claimed.

Claims 38-53, 60-64, and 70-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rizoiu et al (WO '928) in combination with Dressell and the admitted orior art of configuring devices for and using devices for the removal of fat in joints or the abdomen since these are known sites of fat tissue; to employ sterile fluids, since this prevents infection when operating on internal tissue; to construct the device from medical grade plastics, since this is a notorious material for medical devices; and to construct the device of stainless steel, since this is a notorious material for medical devices and is inert. Rizoiu et al teach a tissue removal device and method with hydrokinetic energy generated by the claimed lasers and using water, epinephrine and/or anesthetic as the fluid. Dressell teaches the removal of fat tissue using a cannula which delivers laser energy to the tissue within the cannula. It would have been obvious to the artisan or ordinary skill to employ the hydrokinetic energy generators and steps and fluids of Rizoiu et al (WO '928) in the method and device of Dressell, since the hydrokinetic tissue removal method of Rizoiu et al (WO '928) produces less heat, and thus would prevent damage to nearby healthy tissue; or to employ the cannula delivery system and steps of Dressell in the device and method of Rizoiu et al (WO '928), since Rizoiu et al (WO '928) teaches that the device and method can be used on many kinds of tissue and can include many different types of instruments; and in either case, to employ the method on and configure the device for removal of

fat tissue in joints or the abdomen since these are known sites of fat tissue, official notice of which has already been taken, to employ sterile fluids, since this prevents infection when operating on internal tissue, official notice of which has already been taken, to construct the device from medical grade plastics, since this is a notorious material for medical devices, official notice of which has already been taken, and to construct the device of stainless steel, since this is a notorious material for medical devices and is inert, official notice of which has already been taken; and to configure the device to generate the atomized fluid particles distally of the cannula opening, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result, and would prevent the remaining tissue from being damaged by being jabbed by the cannula end, thus producing a device and method such as claimed.

Claims 55-59, 67-69 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rizoiu et al (WO '928) in combination with Dressell as applied to claims 38-53, 60-64, and 70-74 above, and further in combination with Kittrell et al. Kittrell et al teach a tissue removal device with imaging capabilities. It would have been obvious to the artisan of ordinary skill to provide the infrared imaging device of Kittrell et al. in the device of Rizoiu et al (WO '928) in combination with Dressell since this would enable the surgeon to assure that the tissue is kept at a safe temperature, since this will minimize the damage to nerves and blood vessels, thus producing a device such as claimed.

Applicant's arguments filed July 20, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 38-75 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330